

# PSJ3

## Exhibit 13

## Message

**From:** Kevin Nicholson [KNicholson@NACDS.org]  
**Sent:** 4/22/2011 3:36:45 PM  
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**Subject:** Policy Council  
**Attachments:** RxEpidemicResponse.pdf

Dear Policy Council: This week, the Obama Administration—specifically the Office of National Drug Control Policy, HHS, FDA, and DEA—released its national strategy to address prescription drug misuse and abuse. The Administration's plan highlights the rise of prescription drug misuse and recommends several initiatives to prevent and combat drug diversion, enhance drug disposal efforts, and address "doctor shopping" and "pill mills." A copy of the Plan is attached.

**NACDS has not identified any major concerns with the Administration's Plan. Please advise if you see any concerns. Please respond with any concerns by April 29. A summary is below. Thanks.**

#### Introduction

The strategy includes four major areas to reduce prescription drug abuse: **education, monitoring, disposal, and enforcement.**

1. **Education of the public and healthcare providers** about dangers of prescription drug abuse, and ways to properly dispense, store, and dispose controlled substances.
2. **Enhancement and increased utilization of prescription drug monitoring programs** to identify “doctor shoppers” and detect therapeutic duplication and drug-drug interactions
3. Development of consumer-friendly and environmentally-responsible **prescription drug disposal programs**
4. **Provide law enforcement agencies with the support and tools** they need to shut down “pill mills” and stop “doctor shoppers”

#### **FDA: Opioid REMS**

Notably, the plan includes FDA's announcement of the long-awaited Risk Evaluation and Mitigation Strategy (REMS) for long-acting and extended-release opioids. **We are pleased to report that FDA has adopted our recommendations to implement this REMS in a step-wise approach that focuses on the prescriber-patient encounter. This is remarkable in that FDA's own expert advisory panel had overwhelmingly rejected this proposed REMS that we supported. The REMS will not impose any new burdens on retail pharmacies, except a requirement to provide patients with Medication Guides (MedGuides).** Currently, there is no proposed time frame for when the new MedGuides will be developed or required, except that the REMS should be in place within 12 months.

Also of note: FDA held a conference call to announce this new REMS. During the call, a representative from a prescriber association questioned FDA whether pharmacists would be required to undergo training or education as the new REMS includes prescriber education and training. Dr. Janet Woodcock replied that **it is FDA's belief that pharmacists are the medication experts and should not need additional training and education to dispense controlled substances. FDA is listening to us!**

#### **Education & Training**

- Work with Congress to require **mandatory prescriber training before a prescriber could be eligible for a DEA number**
- Work with state boards (pharmacy, medical, nursing, dental) to require education curricula and continuing education on the safe and appropriate use of opioids
- Other elements focus on prescriber and public education materials, **including enlisting chain pharmacies to disseminate such materials**

#### **Tracking & Monitoring**

- Work with states to **establish a prescription drug monitoring program (PMP) in every state, including mandatory prescriber and dispenser training.**
- Work to expand PMPs across state lines
- Work with Congress to fund NASPER
- Explore feasibility of reimbursing prescribers for checking the PMP before writing a prescription
- Evaluate utility of using PMPs to reduce Medicare and Medicaid fraud
- Issue final DEA rule for electronic prescribing of controlled substances
- Explore how HIT can assist with improving prescription drug abuse information

#### **Drug Disposal:**

- The drug disposal initiatives focus on DEA's upcoming NPRM on prescription drug disposal, government-sponsored take-back events, and public education and awareness about both.

#### **Enforcement**

- Increase law enforcement training
- Enforcement action against pain clinics
- Develop and disseminate a model pain clinic regulation law, which would include counterfeit-resistant prescription pads
- Increase intelligence-gathering and remove barriers to investigations
- Use PMP data to identify criminal prescribers and “doctor shoppers” and reporting their identities to prescribers, pharmacies, law enforcement, and insurance providers

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